

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of:

Karen UHLMANN et al

Appln. No.: 10/823,784

Filed: April 14, 200

For: METHOD OF DETECTING  
EPIGENETIC BIOMARKERS...

Atty. Docket: UHLMANN =1a

) Conf. No.: 4952

) Art Unit: 1645

) Examiner:

) Washington, D.C.

) March 11, 2005

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Randolph Building, Mail Stop Amendments  
401 Dulany Street  
Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[X] B. before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114.

[X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:

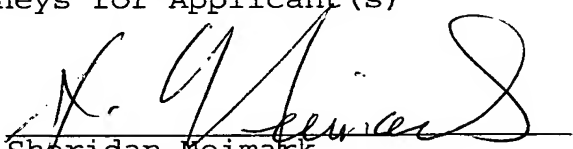
[X] 3. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

4. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK  
Attorneys for Applicant(s)

By:

  
Sheridan Neimark  
Registration No. 20,520

:jaa

G:\BN\A\ANDT\Ulhman1a\PTO\IDS 11mr05.doc  
624 Ninth Street, N.W., Suite 300  
Washington, D.C. 20001-5303  
Telephone: (202) 628-5197  
Facsimile: (202) 737-3528

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of 3

**Complete if Known**

Application Number	10/823,784
Filing Date	April 14, 2004
First Named Inventor	Karen UHLMANN et al
Group Art Unit	1645
Examiner Name	
Attorney Docket Number	UHLMANN =1A

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AA	ANTHONY, et al, "Mutation and methylation analysis of the transforming growth factor $\beta$ receptor II gene in polycythaemia vera", British Journal of Haematology. (2001) 115:872-880.	
	AB	BALOG, et al, "Parallel assessment of CpG methylation by two-color hybridization with oligonucleotide arrays", Analytical Biochemistry (2002) 309:301-310.	
	AC	BAUMER, et al, "A novel MSP/DHPLC method for the investigation of the methylation status of imprinted genes enables the molecular detection of low cell mosaicisms", Human Mutation (2001), 17:423-430.	
	AD	BIRD, Adrian and Edwin Southern, "Use of restriction enzymes to study Eukaryotic DNA methylation: I. The methylation pattern in ribosomal DNA from <i>Xenopus laevis</i> ", J. Mol. Biol. (1978) 111:27-47.	
	AE	CEDER, et al, "Direct detection of methylation cytosine in DNA by use of the restriction enzyme MspI", Nucleic Acids Research (1979) 6(6):2125-2132.	
	AF	CHURCH, George. and Walter Gilbert, "Genomic sequencing", Proc. Natl. Acad. Sci. USA (April 1984), 81:1991-1995.	
	AG	DAHL, Christina and Per Guldberg, "DNA methylation analysis techniques", Biogerontology (2003), 4:233-250.	
	AH	DENG, et al, "Simultaneous detection of CpG methylation and single nucleotide polymorphism by denaturing high performance liquid chromatography", Nucleic Acids Research. (2002). 30(3):e13, (6pages).	
	AI	FRITZSCHE, et al, "The use of permanganate as a sequencing identification for 5-methylcytosine residues in DNA", Nucleic Acids Research (1987). 15(14):5517-5528.	
	AJ	FRAGA, Mario and Manel Esteller, "DNA methylation: A profile of methods and applications", BioTechniques (September 2002). 33:632-649.	
	AK	FROMMER, et al, "A genomic sequencing protocol that yields a positive display of 5-methylcytosine residues in individual DNA strands", Proc. Natl. Acad. Sci. USA (March 1992), 89:1827-1831.	
	AL	FUKUHARA, et al, "Use of the polymerase chain reaction to detect hypermethylation in the calcitonin gene. A new, sensitive approach to monitor tumor cells in acute myelogenous leukemia", Leukemia Research. (1992). 16(10):1031-1040.	

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2

of 3

**Complete if Known**

Application Number	10/823,784
Filing Date	April 14, 2004
First Named Inventor	Karen UHLMANN et al
Group Art Unit	1645
Examiner Name	
Attorney Docket Number	UHLMANN =1A

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AM	EADS, et al, "MethylLight: a high-throughput assay to measure DNA methylation", Nucleic Acids Research. (2000). 28(8):e32:l-viii.	
	AN	EL-MAARRI, et al, "A rapid quantitative, non-radioactive bisulfite-SnuPE-IP RP HPLC assay for methylation analysis at specific CpG sites", Nucleic Acids Research (2002). 30(6):e25@4 pages).	
	AO	HEISKANEN, et al, "A novel methods to quantitate methylation of specific genomic regions", PCR Methods and Applications ((1994). 4:26-30.	
	AP	HERMAN, et al, "Methylation-specific PCR: A novel PCR assay for methylation status of CpG islands", Proc. Natl. Acad. Sci USA. (1996). 93:9821-9826.	
	AQ	GONALGO, M.L. and P. Jones, "Rapid quantitation of methylation differences at specific sites using methylation-sensitive single nucleotide primer extension (Ms-SnuPE)", Nucleic Acids Research. (1997). 25:2529-2531.	
	AR	LAIRD, Peter, "The power and the promise of DNA methylation markers", Cancer. (April 2003). 3:253-250.	
	AS	MARTIN, et al, "An analytical method for the detection of methylation differences at specific chromosomal loci using primer extension and ion pair reverse phase HPLC", Human Mutation. (2002). 20:305-311.	
	AT	McGREW, Michael, and Nadia Rosenthal, "Quantitation of genomic methylation using ligation-mediated PCR", BioTechniques. (1993). 15(4):722-729.	
	AU	OHMORI, et al, "Detection of 5-methylcytosine in DNA sequence", Nucleic Acids Research. (1978). 5(5):1479-1484.	
	AV	PAUL, Cheryl, and Susan Clark, "Cytosine methylation: Quantitation by automated genomic sequencing and GENESCAN <sup>TM</sup> analysis", BioTechniques. (1996). 21(1):126-133.	
	AW	PFEIFER, et al, "Genomic sequencing and methylation analysis by ligation mediated PCR", Science. (1989). 246:810-812.	
	AX	POGRIBNY, et al, "A sensitive new method for rapid detection of abnormal methylation patterns in global DNA and within CpG islands", Biochemical and Biophysical Research Communications. (1999). 262:624-628.	

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3

of 3

**Complete if Known**

Application Number	10/823,784
Filing Date	April 14, 2004
First Named Inventor	Karen UHLMANN et al
Group Art Unit	1645
Examiner Name	
Attorney Docket Number	UHLMANN =1A

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AY	BURRI, Nathalie, and Pascal Chaubert, "Complex methylation patterns analyzed by single-strand conformation polymorphism", BioTechniques. (1999). 26(2):232-234.	
	AZ	REIN, et al, "Identifying 5-methylcytosine and related modifications in DNA genomes". Nucleic Acids Research. (1998). 26(10):2255-2264.	
	BA	SADRI, Ramin, and Peter Hornsby, "Rapid analysis of DNA methylation using new restriction enzyme sites created by bisulfite modification", Nucleic Acids Research. (1996). 24(24):5058-5059.	
	BB	SANO, et al, "Identification of 5-methylcytosine in DNA fragments immobilized on nitrocellulose paper", Proc. Natl. Acad. Sci. USA. (June 4 1980). 77(6):3581-3585.	
	BC	STEIGERWALD, et al, "Ligation-mediated PCR improves the sensitivity of methylation analysis by restriction enzymes and detection of specific DNA strand breaks", Nucleic Acids Research. (1990). 18(6):1435-1439.	
	BD	WAALWIJK, C., and R.A. Flavell, "DNA methylation at a CCGG sequence in the large intron of the rabbit $\beta$ -globin: Tissue-specific variations", Nucleic Acids Research. (December 1978). 5(12):4631-4641.	
	BE	WILSON, et al, "Genomic 5-methylcytosine determination by <sup>32</sup> P-postlabeling analysis", Analytical Biochemistry. (1986). 152:275-284.	
	BF	XIONG, Zhenggang, and Peter Laird, "COBRA: A sensitive and quantitative DNA methylation assay", Nucleic Acids Research. (1997). 25(12):2532-2534.	
	BG	YAN, et al, "Dissecting complex epigenetic alterations in breast cancer using CpG island microarrays", Cancer Research. (December 1, 2001). 61:8375-8380.	

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.